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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,848	03/29/2006	Tai-Wha Chung	1877-1001	2217

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EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	**PAPER NUMBER**
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,848	CHUNG ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-18* is/are pending in the application.

4a) Of the above claim(s) *9-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III, claims 6-8 in the reply filed on 25 October 2007 is acknowledged. The traversal is on the ground(s) that Group IV, claims 9-18 are so closely related to elected claims 6-8 that these claims should be examined together. This is not found persuasive because the claims of group IV are directed to a diagnostic test strip that is neither required nor recited in claims 6-8. Even though the monoclonal antibody used in these claims are similar, the method of using them are completely different. The method of Group III does not require the device the Group IV.

2. Claims 9-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 25 October 2007.

3. Claims 6-8 are under consideration.

Specification

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Method for diagnosing liver diseases.

Claim Rejections - 35 USC § 112, first paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 6-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the detection of chronic hepatitis, liver cirrhosis and hepatocarcinoma with liver cirrhosis using mAb KCTC 10261 to detect AsAGP, does not reasonably provide enablement for the diagnosis of any and all liver diseases using any other monoclonal antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 6-8 are directed to a method for diagnosing a liver disease comprising the detection of asialo alpha-1-acid glycoprotein (AsAGP) in blood or serum using a monoclonal antibody, and specifically KCTC 10261 BP.

The specification discloses the detection of AsAGP in blood samples from sources including normal, non-hepatic disease, acute hepatitis, chronic hepatitis, liver cirrhosis and hepatocarcinoma with liver cirrhosis, using KCTC 10261; however, it is unclear from the results and discussion therein how it was determined that "a liver disease" can be diagnosed using the data presented. The specification states that the

cutoff value for diagnosing a liver disease is 1.50 ug/ml when mAb KCTC 10261 is used. Normal and non-hepatic samples have an average of 1.00 ug/ml, and in patient groups suffering from acute hepatitis, chronic hepatitis, liver cirrhosis and hepatocarcinoma with liver cirrhosis, the blood level of AsAGP averaged 1.33 ug/ml, 1.63 ug/ml, 3.12 ug/ml and 3.64 ug/ml. The specification also states that about 10% of the control samples have AsAGP value over 1.50 ug/ml.

It would appear from this data that the specification is only enabled for the detection of chronic hepatitis, liver cirrhosis and hepatocarcinoma with liver cirrhosis using mAb KCTC 10261 and only when the detected level of AsAGP is above 1.50 ug/ml. The specification is not enabled for the diagnosis of any and all liver diseases using any monoclonal antibody except for MAb KCTC 10261.

Therefore, it is maintained that one of ordinary skill in the art could not make and use the invention as claimed without undue experimentation.

Claim Rejections - 35 U.S.C. 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to provide an adequate written description of the invention and fails to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological materials are: (1) known and readily available to the public; (2) reproducible from the written description; or, (3) deposited in compliance with the criteria set forth in 37 CFR " 1.801-1.809."

The specification lacks complete deposit information for the hybridoma AS 16.89 deposited as KCTC 10261 BP because it is not clear that the cell line possessing the properties of the hybridoma designated AS 16.89 is known and publicly available or can be reproducibly isolated without undue experimentation, and because the invention of claim 7 uses the monoclonal antibody produced by that hybridoma, a suitable deposit for patent purposes is required. Accordingly, filing of evidence of the reproducible production of the cell lines and antibodies necessary to practice the instant invention or filing of evidence of deposit is required. Without a publicly available deposit of the above cell lines, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell lines is an unpredictable event. Applicants must comply with the criteria set forth in 37 CFR 1.801-1.809.

If the deposits are made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or

her signature and registration number, stating that the specific cell lines have been deposited under the Budapest Treaty, that the cell lines will be irrevocably and without restriction or condition released to the public upon the issuance of a patent and that the cell lines will be replaced should they ever become non-viable, would satisfy the deposit requirement made herein.

If the deposits have not been made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in 37 CFR 1.801-1.809, applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- the deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- the deposits were viable at the time of deposit; and,
- that the deposits will be replaced if they should ever become non-viable.

9. In the instant case, it is not clear that the deposit was made under the terms of the Budapest Treaty, nor is there available a viability statement, i.e. one certifying that the

deposit was viable at the time of the deposit or a certificate verifying such from the depository. As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit along with the necessary statements in order to meet the criteria se forth in 37 CFR 1.801-1.809.

Applicant's attention is directed to In re Lundak, 773 F.2nd. 1216, 227 USPQ 90 (CAFC 1985) and 37 CRF 1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 U.S.C. 112, second paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite because the claim is incomplete. There is no correlation between measuring the amount of AsAGP in a test sample and the diagnosis of a liver disease. Furthermore, it is unclear how the measured amount of AsAGP is related to a liver disease. According to the specification oat pages 20 and 21, a measured amount

above a cut off value of 1.50 μg/ml is diagnostic for a liver disease, however, this is not recited in the claims.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (f) he did not himself invent the subject matter sought to be patented.

13. Claims 6-8 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

A publication by Song et al., ("Elevation of serum asialo-alpha-1 glycoprotein concentration in patients with hepatic cirrhosis and hepatocellular carcinoma as measured by antibody-lectin sandwich assay." *Hepatology Research.* 26 (2003): 311-317) discloses the invention in its entirety.

The authorship of this paper differs from the inventorship of the instant application, therefore, it is unclear whether application invent the claimed subject matter.

14. Claims 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Toyama et al (EP 0 199 196).

Claims 6 and 8 are directed to a method for detecting asialo alpha-1 acid glycoprotein in blood or serum using a monoclonal antibody. Even though claim 6 recites a method of diagnosing a liver disease by detecting AsAGP, claim 6 lacks any diagnostic steps and is currently limited only to the measurement of AsAGP.

Toyama teaches such a method. Toyama teaches the production of monoclonal antibodies specific for AsAGP and using the same to detect AsAGP in blood samples. See example 1, column 6 and columns 10-13.

15. Claims 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Fraeyman et al., (Hybridoma. 1987. Vol. 6, No. 6, pp. 565-574.).

Fraeyman discloses the production of monoclonal antibodies and eliza assay using the same to detect asiolo alph -1 acid glycoprotein. See pages 566 and 567. Fraeyman discloses that it has been known that serum concentration of AGP is influenced by various stimuli including some liver diseases and that chronic inflammation is characterized by a significant increase. See pages 565 and 566.

16. Claims 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Song et al., (Clinical Chemistry, Vol. 47, No. 6, Supplement, 2001. A152).

Song discloses serum asialoglycoprotein concentration in patients with hepatic diseases and teaches the production of monoclonal antibody to alpha-1-acid glycoprotein. Song teaches the use of this Mab to detect elevated levels of ASAGP in serum specimens of patients suffering from cirrhosis and hepato carcinoma using sandwich immunoassays.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday -- Thursday from 9:00 a.m. - 3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
12/18/07